UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

VERONICA MILLER et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. CIV-19-1200-G**
	)	
C. R. BARD, INC.,	)	
	)	
Defendant.	)	

ORDER

Plaintiffs Veronica Miller and Timothy D. Miller initiated this products liability action in the United States District Court for the Southern District of West Virginia as part of a multidistrict litigation. *See* Am. Short Form Compl. (Doc. No. 5); *In re: C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187 (S.D.W. Va.). During coordinated pretrial proceedings, the parties filed dispositive and *Daubert* motions, including Defendant's Motion for Summary Judgment (Doc. No. 32), Plaintiffs' Motion to Exclude the Opinions and Testimony of Thomas Giudice, M.D., M.S. (Doc. No. 34), and Defendant's Motion to Exclude the Opinions and Testimony of Matthew Karlovsky, M.D., F.A.C.S. (Doc. No. 42). Each of these motions is now at issue.[1] *See* Doc. Nos. 37-41, 43-45. The District Court for the Southern District of West Virginia transferred the matter to this Court in December 2019. *See* Transfer Order (Doc. No. 46). Having reviewed the parties' submissions and the relevant record, the Court grants in part and denies in part

[1] Because Defendant's request to exclude Dr. Karlovsky's opinions is pertinent to the Motion for Summary Judgment, the Court has addressed that motion by separate order issued this same date.

Defendant's Motion for Summary Judgment.

I. UNDISPUTED MATERIAL FACTS

The following facts are undisputed. Plaintiff Veronica Miller is an Oklahoma resident diagnosed by her doctor, Larry Houk, MD, with genital prolapse, rectocele, cystocele, and vaginal descent. Def.'s Mot. Ex. 5 (Doc. No. 32-5) at 15, 17; Def.'s Mot. Ex. 1 (Doc. No. 32-1) at 6. In December 2007, Dr. Houk recommended and performed a surgical repair using Avaulta Plus mesh, which was manufactured by Defendant C. R. Bard, Inc. Def.'s Mot. Ex. 5, at 17-18; Def.'s Mot. Ex. 1, at 6. Ms. Miller's surgery was initially successful, but she began experiencing vaginal pain in 2012. Def.'s Mot. Ex. 1 at 7. Dr. Houk eventually removed the mesh in 2013. Def.'s Mot. Ex. 5, at 24-25. After removal, Ms. Miller began experiencing further health problems that were ultimately diagnosed to be caused by a fistula, a hole that formed between her rectum and vagina. *Id.* at 26. Plaintiffs filed this suit, alleging that Defendant's mesh caused her injuries.

II. STANDARD OF REVIEW

Summary judgment is a means of testing in advance of trial whether the available evidence would permit a reasonable jury to find in favor of the party asserting a claim. The Court must grant summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A party that moves for summary judgment has the burden of showing that the undisputed material facts require judgment as a matter of law in its favor. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). To defeat summary judgment, the nonmovant need not convince the Court that it will prevail at trial, but it must cite sufficient evidence

admissible at trial to allow a reasonable jury to find in the nonmovant's favor—i.e., to show that there is a question of material fact that must be resolved by the jury. *See Garrison v. Gambro, Inc.*, 428 F.3d 933, 935 (10th Cir. 2005). The Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

Parties may establish the existence or nonexistence of a material disputed fact by:

- citing to "depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials" in the record; or

- demonstrating "that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact."

Fed. R. Civ. P. 56(c)(1)(A), (B). While the Court views the evidence and the inferences drawn from the record in the light most favorable to the nonmoving party, *see Pepsi-Cola Bottling Co. of Pittsburg, Inc. v. PepsiCo, Inc.*, 431 F.3d 1241, 1255 (10th Cir. 2005), "[t]he mere existence of a scintilla of evidence in support of the [nonmovant's] position will be insufficient; there must be evidence on which the [trier of fact] could reasonably find for the [nonmovant]." *Liberty Lobby*, 477 U.S. at 252.

III. ANALYSIS

Plaintiff Veronica Miller brings the following claims: strict liability for manufacturing defects, design defects, and failure to warn; negligent design, manufacture, marketing, inspecting, labelling, packaging, and selling; breach of express warranty; and breach of implied warranty. Plaintiff Timothy D. Miller brings a claim of loss of

consortium. Plaintiffs seek both compensatory and punitive damages. *See* Am. Short Form Compl. at 5; Master Long Form Compl., *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 10-mdl-2187 (S.D.W. Va. Sept. 26, 2012) (Doc. No. 352). There is no dispute that Oklahoma law governs Plaintiffs' claims.

Defendant has moved for summary judgment on all claims. Plaintiffs' response addresses only the design defect and failure-to-warn claims. This omission limits, but does not entirely obviate, the Court's review of the remaining claims. *See Murray v. City of Tahlequah*, 312 F.3d 1196, 1200 (10th Cir. 2002) (directing that when a nonmoving party fails to respond to a motion for summary judgment, the court may not grant the motion without first determining whether the moving party "has met its initial burden of demonstrating that no material issues of fact remain for trial and the moving party is entitled to judgment as a matter of law" (internal quotation marks omitted)).

A. Strict Products Liability Claims

A plaintiff suing a manufacturer under a strict products liability theory must establish: "(1) that the product caused plaintiff's injury; (2) that the defect existed in the product at the time of sale or at the time it left the [manufacturer's] possession and control; and (3) that the defect made the product unreasonably dangerous." *Wheeler v. HO Sports Inc.*, 232 F.3d 754, 756 (10th Cir. 2000) (citing *Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353 (Okla. 1974)); *see Holt v. Deere & Co.*, 24 F.3d 1289, 1292 (10th Cir. 1994). The defect alleged "may be the result of a problem in the product's design or manufacture, or it may be the result of inadequate warnings regarding use of the product." *Wheeler*, 232 F.3d at 757 (internal quotation marks omitted). Here, Plaintiffs have alleged that

Defendant's mesh was defective in all three respects.

1. Manufacturing Defect

When a defect is alleged to stem from the manufacture of the product, the plaintiff must show that the product "deviates in some material way from its design or performance standards." *Id.* (internal quotation marks omitted). Errors in the manufacturing process "are often established by showing that a product, as produced, failed to conform with the manufacturer's specifications." *Id.*

Defendant argues that Plaintiffs have not presented any evidence—from an expert witness or otherwise—indicating that Defendant's mesh was defective due to manufacturing error or that a manufacturing defect caused Ms. Miller's injuries. *See* Def.'s Br. (Doc. No. 33) at 12-13. Defendant also submits evidence that the product at issue in this case was manufactured in accordance with Defendant's specifications and standards. *See* Def.'s Mot. Ex. 6 (Doc. No. 32-6) at 82-85; Def.'s Br. at 13. Plaintiffs offer no argument or evidence in response. Rather, they assert that they "are not disputing whether or not Defendant[']s product[] conformed to its own specifications." Pls.' Resp. (Doc. No. 38) at 6. Accordingly, Plaintiffs have failed to demonstrate a genuine issue of fact as to whether the product was defectively manufactured, and Defendant is entitled to summary judgment on this aspect of Ms. Miller's claim.

2. Design Defect

When a defect is alleged to stem from the design of the product, the plaintiff must show that "1) the product was defective; 2) the product was dangerous to an extent not contemplated by an ordinary consumer; 3) the defect existed when it left the possession

and control of the manufacturer; and 4) the defect proximately caused [the plaintiff's] injuries." *Noll v. Apex Surgical, LLC*, No. CIV-08-1379-D, 2010 WL 2773576, at *3 (W.D. Okla. July 14, 2010) (citing *Ahrens v. Food Motor Co.*, 340 F.3d 1142 (10th Cir. 2003)); *see Wheeler*, 232 F.3d at 758 ("A product is defective in design if something about that design 'renders it less safe than expected by the ordinary consumer.'" (quoting *Lamke v. Futorian Corp.*, 709 P.2d 684, 686 (Okla. 1985)). The plaintiff may rely on circumstantial evidence to support her claim, but a court may "not infer that the injury is of itself proof of the defect." *Kirkland*, 521 P.2d at 1363. And "the mere possibility that a defect caused the injury is not sufficient." *Dutsch v. Sea Ray Boats, Inc.*, 845 P.2d 187, 191 (Okla. 1992).

Defendant argues two independent bases for summary judgment as to the design defect claim: (1) that the Avaulta Plus mesh satisfied the requirements for unavoidably unsafe products set forth in comment *k* to section 402A of the Restatement (Second) of Torts, as adopted by the Oklahoma Supreme Court in *Tansy v. Dacomed Corp.*, 890 P.2d 881, 885-87 (Okla. 1994);[2] and (2) that Plaintiffs cannot establish an unreasonably dangerous aspect of the design that proximately caused Ms. Miller's injuries. *See* Def.'s Br. at 13-19; Def.'s Reply (Doc. No. 41) at 2-4, 8-11.

The Court confines its analysis to the latter point because Plaintiffs fail to meaningfully support their allegation of a design defect. For its part, Defendant has

[2] "[Comment *k*] applies . . . as an affirmative defense in those cases in which the following criteria are met: (1) the product is properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe." *Tansy*, 890 P.2d at 886.

supplied expert opinion that the Avaulta Plus mesh was not defective in design. *See* Def.'s Mot. Ex. 6 (Doc. No. 32-6) at 85 (Expert Report of Dr. Maureen Reitman). In discussing comment *k*, Plaintiffs state that erosion of the Avaulta Plus mesh was the cause of Ms. Miller's injury. *See* Pls.' Resp. at 8. But at no point in their Response do Plaintiffs cite any proper Rule 56 material to identify erosion—or any other flaw—as a defect that rendered Avaulta Plus mesh less safe than an ordinary customer might expect. *See* Fed. R. Civ. P. 56(c)(1)(A) (requiring citation to particular evidentiary material, which stands in the place of evidence that may be presented at trial, to support the existence or nonexistence of a material fact); *Wheeler*, 232 F.3d at 758. Plaintiffs come closest to the point when citing the deposition testimony of Dr. Matthew Karlovsky that erosion of the Avaulta Plus mesh implanted in Ms. Miller caused her to suffer chronic inflammation, pain, and fistula. *See* Pls.' Resp. at 8-9. Dr. Karlovsky, however, expressly disclaimed that he was offering an opinion about whether there was any design defect in Avaulta Plus mesh. While Dr. Karlovsky opined throughout his deposition about the relative strengths and weaknesses of different types of mesh products and their composition, when questioned directly regarding his opinion as to whether Avaulta Plus mesh was defective he stated: "I'm not arguing the defect—whether there is or isn't—in the product. There may be defects; there may not be defects." Pls.' Resp. Ex. 2 (Doc. No. 38-2) at 67-68. Dr. Karlovsky repeated that he was "not making any defect arguments." *Id.* at 68. And when asked if he was offering any opinion regarding the design of the Avaulta Plus product, Dr. Karlovsky reiterated that he was not. *Id.* at 142.

In sum, Defendant has supplied expert opinion that the Avaulta Plus mesh was not

defective in design and, in response, Plaintiffs point to no proper Rule 56 material identifying a specific design defect that rendered Avaulta Plus mesh less safe than an ordinary customer might expect. This is insufficient to establish the existence of a disputed fact as to whether Avaulta Plus mesh suffered a design defect that caused Ms. Miller's injuries. Therefore, Defendant is entitled to summary judgment on this aspect of Ms. Miller's claim.

3. Failure to Warn

When an injury is alleged to have been caused not by a defect in a product's manufacture or design, but an unavoidable danger inherent to the product, the plaintiff must show that the manufacturer failed "to warn the consumer of potential dangers which may occur from the use of the product" and that the manufacturer knew or should have known that such hazards exist. *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982). Further, to establish causation, a plaintiff must also show that the failure to warn was "a substantial contributing factor in bringing about the harm in question." *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1017 (10th Cir. 2001).

These requirements are modified, however, when considering a medical drug or device for which a physician stands as an intermediary between the product's manufacturer and its ultimate user, the patient. If a failure-to-warn claim is asserted against a manufacturer of a medical device, and the manufacturer supplied the device to a surgeon rather than to the patient directly, Oklahoma's learned intermediary doctrine applies. *See Edwards v. Basel Pharms.*, 933 P.2d 298, 300 (Okla. 1997). Under this doctrine, manufacturers are shielded from liability if the manufacturer adequately warns the surgeon

who implants the medical device of a potential danger. *See id.* Thus, for Ms. Miller to prevail on her failure-to-warn claim, Plaintiffs must show that Defendant did not adequately warn Dr. Houk of potential dangers to Ms. Miller from the implantation of Avaulta Plus mesh. *See id.*; *Eck*, 256 F.3d at 1018.

Plaintiffs have alleged that warnings supplied to Dr. Houk by Defendant, notably in an Instructions For Use ("IFU") insert and a patient brochure, were inadequate. Defendant in its Motion argues that the warnings it gave were sufficient, pointing to Dr. Houk's deposition testimony that the IFU warned of what Defendant contends are the known complications associated with implantation, including erosion, inflammation, mesh extrusion, dyspareunia, and fistula. Def.'s Br. at 19-21; Pls.' Resp. Ex. 3 (Doc. No. 38-3) at 43-45, 48; Def.'s Mot. Ex. 7 (Doc. No. 32-7) at 5 (Avaulta Plus IFU warning that potential adverse reactions include erosion, inflammation, sensitization, dyspareunia, fistula formation, extrusion, and perforations of rectum, among others).

Plaintiffs do not dispute that the IFU identifies adverse complications Ms. Miller claims to have suffered. Plaintiffs contend, however, that these warnings were insufficient to communicate the severe long-term risks involved with using Defendant's mesh product.[3] In support of this contention, Plaintiffs cite Dr. Karlovsky's proposed opinion testimony that Defendant, in the IFU and patient brochure, "failed to convey the proper level of

[3] In the allegations related to their failure-to-warn claim, Plaintiffs refer to a lack of training given by Defendant to Dr. Houk on the proper implantation procedures. Plaintiffs' expert noted only the IFU and patient brochure as the sources of information that would support a failure-to-warn claim, however. *See* Pls.' Resp. Ex. 1 (Doc. No. 38-1) at 23; Pls.' Resp. Ex. 2 (Doc. No. 38-2) at 118-19. The Court will therefore focus only on alleged deficiencies in the IFU and the brochure.

uncertainty about the long term unknown risks of its Avaulta mesh and the higher risks of wound healing complications in patients taking steroids or who have diabetes." Pls.' Resp. Ex. 1, at 23. Dr. Karlovsky's proposed testimony is discussed more fully in the Court's Order on Defendant's Motion to Exclude the Opinions and Testimony of Matthew Karlovsky, M.D., F.A.C.S.

Defendant in its Motion further argues that Dr. Houk would not have read and heeded alternative warnings suggested by Plaintiffs. To establish causation, Plaintiffs must show that "had [Defendant] issued a proper warning to [Dr. Houk], he would have altered his behavior and the injury would have been avoided." *Eck*, 256 F.3d at 1018 (internal quotation marks omitted). Under Oklahoma law, when a plaintiff shows that she was injured by use of a product for which the warning given to a learned intermediary was inadequate, a rebuttable presumption arises that if an adequate warning had been given then the intermediary would have read it and "acted so as to minimize the risks." *Id.* (internal quotation marks omitted). The defendant manufacturer may rebut the presumption by showing that the intermediary would not have read or not have heeded the warning. If the defendant manufacturer rebuts the presumption, the burden then shifts back "rather heavily" onto the plaintiff to present evidence "sufficient to submit the case to a jury to determine if defendant['s] alleged inadequate warnings were a proximate cause of [the plaintiff's] injuries." *Id*. (alterations and internal quotation marks omitted).

Here, Defendant contends that, even assuming Plaintiffs have established that Ms. Miller was injured by use of the Avaulta Plus mesh and that the warnings given to Dr. Houk were inadequate, the presumption of causation-in-fact should be found (based on

undisputed material fact) to be rebutted. To that end, Defendants point to Dr. Houk's deposition testimony that: (1) the only information Dr. Houk relied on from Defendant was that the mesh product was approved by the Food and Drug Administration and that he based his decision to use Defendant's product on word-of-mouth reports and third-party articles (Pls.' Resp. Ex. 3, at 38, 39-40); and (2) while Dr. Houk initially reviewed some of Defendant's written materials, he usually threw them away because "we'd already talked about it, and I already knew what was in there" (*id.* at 36).

While Defendant focuses on whether a new but revised IFU might have been discarded even if issued, and on the fact that Dr. Houk consulted secondary materials, it remains the case that Dr. Houk testified that he reviewed an Avaulta mesh IFU at some point prior to performing Ms. Miller's surgery. *Id.* at 37. Further, Plaintiffs cite Dr. Houk's deposition testimony that he would not have used Defendant's mesh product if he had known at the time that "many" of his patients would develop "problems." *Id.* at 102.

While a close call, and one affected by the paucity of the briefing, the Court concludes that the evidentiary material cited by Plaintiffs is sufficient to create legitimate factual disputes as to whether the warnings given Dr. Houk were adequate and whether, if an alternative warning had been given by Defendant to Dr. Houk, "he would have altered his behavior and the injury would have been avoided." *Eck*, 256 F.3d at 1018 (internal quotation marks omitted). Accordingly, viewing these factual disputes in Plaintiffs' favor, summary judgment must be denied as to Ms. Miller's failure-to-warn claim.

B. Negligence Claims

Ms. Miller's claims of negligent design, manufacture, marketing, inspecting,

labelling, packaging, and selling are governed by Oklahoma's general negligence standard, which requires "proof of a duty, a breach of that duty, and causation." *Martinez v. Angel Expl., LLC*, 798 F.3d 968, 974 (10th Cir. 2015) (citing *Scott v. Archon Grp., L.P.*, 191 P.3d 1207 (Okla. 2008)).[4] Defendant argues that these negligence claims fail for lack of evidence. Plaintiffs did not expressly address the claims in their response.

As discussed in relation to Ms. Miller's strict liability claims, Plaintiffs have failed to demonstrate a genuine issue of fact as to the existence of a defect in design or manufacture. *See supra* sections III.A.1, III.A.2. As the existence of an actual defect is essential to establishing breach of duty in both a negligent design and a negligent manufacture cause of action, Defendant is entitled to summary judgment on these claims. *See Bruce v. Martin-Marietta Corp.*, 418 F. Supp. 829, 834-35 (W.D. Okla. 1975) (explaining that recovery in a products liability case is contingent upon a showing that the product is defective, regardless of whether liability is based on the theory of negligence, breach of warranty, or strict liability in tort).

The negligent marketing, inspecting, labelling, packaging, and selling claims likewise fail, as Plaintiffs have provided no argument or evidence in support. Defendant is entitled to summary judgment on these claims.

C. Breach of Express and Implied Warranty Claims

Defendant is also entitled to summary judgment on Ms. Miller's express and implied

[4] In Oklahoma, a plaintiff injured by a defective product is not foreclosed from asserting a freestanding negligence claim in addition to a claim of strict products liability. *See Braswell v. Cincinnati Inc.*, 731 F.3d 1081, 1093 n.4 (10th Cir. 2013).

warranty claims. First, Oklahoma law does not recognize implied warranty claims for products liability actions outside the context of the Uniform Commercial Code, as that theory of liability has "merged into the theory and doctrine of manufacturers' products liability." *Kirkland*, 521 P.2d at 1355; *see id*. at 1364-65. As Plaintiffs raise no arguments or evidence implicating the Uniform Commercial Code, the implied warranty claim fails. Second, Ms. Miller's breach of express warranty claim fails because Plaintiffs have not identified any express warranty or established that she or Dr. Houk relied on a warranty made by Defendant that was later breached. *See Speed Fastners, Inc. v. Newsom*, 382 F.2d 395, 397 (10th Cir. 1967).

D. Mr. Miller's Loss of Consortium Claim

Mr. Miller's claim for loss of consortium is derivative of Ms. Miller's claims. To the extent the Court has found Defendant to be entitled to summary judgment on Ms. Miller's claims, Mr. Miller's loss of consortium claim likewise fails. *See Rishell v. Jane Phillips Episcopal Mem'l Med. Ctr.*, 94 F.3d 1407, 1411 (10th Cir. 1996) (explaining that "under Oklahoma law the interest of the husband in recovering damages for loss of consortium arising from injuries to his wife is derivative of the wife's right to recover"); *accord Schumaker v. G.M. Hosp. Mgmt., Inc.*, No. 90-6017, 1991 WL 50181, at *1 (10th Cir. Apr. 4, 1991). To the extent Mr. Miller's loss of consortium claim is based on Ms. Miller's strict liability failure-to-warn claim, summary judgment is denied.

CONCLUSION

The undisputed facts show that Plaintiffs cannot establish essential elements of their claims. Defendant's Motion for Summary Judgment (Doc. No. 32) therefore is GRANTED

as to Plaintiffs' claims with the exception of (1) Veronica Miller's failure-to-warn claim, and (2) Timothy D. Miller's loss of consortium claim to the extent it is based on Veronica Miller's failure-to-warn claim.[5]

IT IS SO ORDERED this 19th day of March, 2021.

Charles B. Goodwin

CHARLES B. GOODWIN
United States District Judge

[5] At the status and scheduling conference held in this matter on August 5, 2020, the parties requested that the Court reopen expert discovery to allow the parties to retain expert pathologists. The parties advised the Court that the contemplated expert discovery would not affect disposition of the motion for summary judgment. Plaintiffs later requested, and the Court granted, an additional extension of the expert discovery deadline. *See* Doc. Nos. 72, 74. Plaintiffs did not request that the Court defer consideration of the motion for summary judgment until such discovery was completed.